

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
Complainant

v.

Joe Eideh
d/b/a 7-Eleven 34428,

Respondent.

Docket No. C-15-3153
FDA No. FDA-2015-H-2239

Decision No. CR4508

Date: January 15, 2016

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Joe Eideh d/b/a 7-Eleven 34428 for five violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a thirty-six month period. Specifically, CTP alleges that 7-Eleven 34428 violated the Act by impermissibly selling cigarettes to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$5,000 civil money penalty on Respondent 7-Eleven 34428 and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint. In its answer, Respondent admitted to all of the allegations, but asserted that the civil money

penalty was too high. On August 24, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. CTP filed its pre-hearing exchange on November 10, 2015. Respondent's pre-hearing exchange was due on December 1, 2015, and to date Respondent has not filed a pre-hearing exchange.

Decision on the Record

Pursuant to 21 C.F.R. § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP submitted one witness declaration. Respondent 7-Eleven 34428 has not submitted direct testimony. Because Respondent 7-Eleven 34428 has not submitted any direct testimony, there is no one for CTP to request to cross-examine. And, since Respondent 7-Eleven 34428 has admitted to all of the allegations, the witness declaration that CTP has submitted is not relevant to the issue of the amount of the civil money penalty. Therefore, I will decide this case on the basis of the written record.

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent 7-Eleven 34428 committed five violations of the Act and its implementing regulations within a thirty-six month period. 7-Eleven 34428 filed an answer to the Complaint that admitted to all of the allegations, but asserted that the civil money penalty was too high. Answer.

The Complaint currently before me involves one prior complaint. The prior complaint was settled by the parties and the Respondent's representative admitted the violations occurred, waived the ability to contest the violations in the future, and stated that he understood that the violations may be counted in determining the total number of violations for future enforcement actions. Complaint ¶ 11. The Complaint currently before me involves two new violations, impermissibly selling cigarettes to a minor and failing to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older. In its Answer, Respondent admitted to these violations. Therefore, Respondent 7-Eleven 34428 has admitted to all violations in the current Complaint.

CTP makes the following uncontested allegations:

- Respondent owns 7-Eleven 34428, an establishment that sells tobacco products and is located at 73 Storey Avenue, Newburyport, Massachusetts 01950. Complaint ¶ 3.

- CTP previously initiated a civil money penalty action, CRD Docket Number C-15-482, FDA Docket Number FDA-2014-H-2008, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, those violations included two violations on August 14, 2013, when Respondent sold cigarettes to a minor and failed to verify, by means of photographic identification, that the purchaser was 18 years of age or older;¹ and two violations on June 11, 2014, when Respondent sold cigarettes to a minor, and failed to verify, by means of photographic identification, that the purchaser was 18 years of age or older. Complaint ¶ 10; November 21, 2014 Complaint ¶ 10.
- The previous civil money penalty action concluded when Joe Eideh, Respondent's authorized representative, settled the action with CTP on Respondent's behalf. Mr. Eideh signed an Acknowledgment Form, dated January 27, 2015, in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on February 5, 2015. Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on March 11, 2015, at approximately 3:36 PM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes" The inspectors also documented that "the minor's identification was not verified before the sale . . . [.]" Complaint ¶ 1.

Respondent 7-Eleven 34428 does not dispute these allegations. Therefore, I find that these facts establish Respondent Joe Eideh d/b/a 7-Eleven 34428's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age.

¹ CTP counted the two violations on August 14, 2013, as one violation.

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on August 14, 2013, June 11, 2014, and March 11, 2015. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

A. II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7-Eleven 34428 is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$5,000, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 13. In its Informal Brief, CTP continues to assert that a \$5,000 civil money penalty is appropriate. Informal Brief of Complainant at 8.

Respondent 7-Eleven 34428 states that: "I understand that my establishment was involve[d] with this violation but the employee did do what [they were] supposed to even though they had received the proper training." Answer.

When determining the amount of a civil money penalty, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." 21 U.S.C. § 303(f)(5)(B).

i. Nature, Circumstances, Extent and Gravity of the Violations

Time and again, Respondent 7-Eleven 34428 has failed to comply with the Act and its implementing regulations. Over the course of the six violations discussed in this Complaint, Respondent has admitted to all six violations²; specifically Respondent has admitted to: three violations of selling tobacco products to minors, and three violations of failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

² I note that CTP's requested civil money penalty is based upon 5 violations.

ii. Respondent's Ability to Pay

CTP is seeking a \$5,000 civil money penalty against Respondent 7-Eleven 34428. CTP asserts that Respondent did not provide evidence that it was unable to pay. In its Answer, Respondent does not assert that he is unable to pay a \$5,000 civil money penalty. CTP has not provided evidence of Respondent's ability to pay and Respondent has not provided evidence to show that it would be unable to pay a \$5,000 penalty.

iii. Effect on Ability to do Business

There is nothing in the evidentiary record that shows the effect a civil money penalty will have on Respondent 7-Eleven 34428's ability to do business. CTP asserts that "Respondent may continue to sell tobacco products and other products at the establishment." Informal Brief of Complainant at 9. CTP also stated that "Respondent did not provide any evidence that this penalty will prevent Respondent from conducting business." *Id.* Respondent has not asserted that this penalty will have an effect on its ability to do business. Neither party has provided evidence of whether a \$5,000 civil money penalty against Respondent would have a substantial effect on Respondent's ability to do business.

iv. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent 7-Eleven 34428 since December 1, 2014 for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-15-482, FDA Docket Number FDA-2014-H-2008, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1). Respondent settled the prior complaint with CTP for an undisclosed penalty amount.

I agree with CTP that "[t]hese *repeat* violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations." *Id.* (emphasis in original). While Respondent has already paid a civil money penalty for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

v. Degree of Culpability

Respondent 7-Eleven 34428 admitted to all violations. Based on Respondent 7-Eleven 34428's own admissions, I hold it fully culpable for all six violations of the Act and its implementing regulations.³

vi. Additional Mitigating Factors

Respondent 7-Eleven 34428 stated that the employee that committed the violation no longer works for the Respondent and that the employee received the proper training. Answer.

vii. Penalty

I note that the record lacks evidence of Respondent's ability to pay a \$5,000 civil money penalty, and that the record does not contain evidence that shows the effect that a \$5,000 civil money penalty would have on Respondent's ability to do business. However, Respondent does not argue that he does not have the ability to pay a \$5,000 civil money penalty, nor does Respondent argue that such a penalty would affect his ability to do business. I acknowledge that the employee that committed the most recent violations no longer works for Respondent. However, based on the foregoing reasoning, I find a penalty amount of \$5,000 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$5,000 against Respondent, Joe Eideh d/b/a 7-Eleven 34428, for five violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a thirty-six month period.

/s/
Steven T. Kessel
Administrative Law Judge

³ I note that CTP's requested civil money penalty is based upon 5 violations.